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Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Attention: Section 8(e) Coordinator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Re: TSCA Section 8(e) Reporting/Notification for Sodium Bromide,
CAS Number: 7647-15-6

COMPANY SANITIZED

Dear Section 8(e) Coordinator:

[ ] submits this notice of substantial risk in accordance with Section 8(e) of the TSCA regulations and EPA's Section 8(e) Statement of Interpretation and Enforcement Policy (43 Fed. Reg. 11110).

[ ] a developmental toxicity study in rats for the product sodium bromide. [ ] The study draft report was recently received by the sponsor for review.

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Sodium bromide technical was administered in water at dosages of 0 (vehicle control), 100, 300, and 1000 mg/kg/day by intragastric intubation to groups of 25 time-mated female rats per group from day 6 to 15 post coitum inclusive. On day 20 post coitum, females were sacrificed and subjected to post mortem examination, litter values determined and fetuses subsequently sexed and examined for visceral or skeletal changes.

At 1000 mg/kg/day, treatment-related developmental and maternal toxicity were observed. Examination revealed higher incidences of fetuses/litter showing absent left kidney, absent left ureter, absent/narrow left uterine horn, distorted ribs,

shorten/absent 13th ribs, irregular ossification of the thoracic vertebral centra, reduced and/or unossified sternebrae, and reduced ossification of one or more cranial centers, than in controls. Maternal toxicity was evidenced by various clinical signs (unsteady gait, poorly coordinated movements, reduced bodytone and hair loss), mortality, decreased bodyweight gain, decreased food consumption (days 18 to 19), and increased food consumption (days 6 to 9 and 14 to 15).

At 300 mg/kg/day, embryofetal toxicity as evidenced by a higher incidence of fetuses showing reduced ossification of various skeletal components compared to controls, and maternal toxicity as evidenced by decreased bodyweight gain during day 16 to 20 were observed.

The dosage level of 100 mg/kg/day was a No-Observed Effect Level (NOEL) for both embryofetal and maternal toxicity.

This notice advises the Agency of new information following review of the draft report. Upon completion, the final report would be submitted to the Agency.

[ ]

Sincerely,

[ ]

[ ]
[ ]